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### **REMARKS**

Claims 1-38 are pending. Claims 1-38 have been rejected. Claims 1, 34, 37 and 39 have been amended. New claim 61 has been added.

For the amendments to claims 1, 33, 37 and 38 and for new claim 61m support in the specification can be found at paragraph 0005, lines 1-4, paragraph 0007, and paragraph 0014 among other places.

No new matter has been added.

#### **1. Objection to the Claims**

The Examiner objected to claim 1 as lacking antecedent basis for the sensor means in line 5. Claim 1 has been amended to obviate the objection.

#### **2. Rejection Under 35 U.S.C. §101**

Claim 34 was rejected under 30 U.S.C. §101 as being directed to non-statutory subject matter because it recites a positive relationship to the human body. Claim 34 has been amended to recite that the holder is adapted to support the tongue as suggested by the Examiner.

#### **3. Rejection Under 35 U.S.C. §102(b) and alternatively under §103(a)**

Claims 1-29, 33-35 and 38 were rejected under 35 U.S.C. §102(b) as being anticipated by Rosenberg et al. (U.S. 4,538,618) or in the alternative under §103(a) as being unpatentable over Rosenberg et al. The Examiner states that with respect to claim 1, Rosenberg discloses a blood flow sensor, i.e. fiber 16, located in a measuring head 2 and an indicator 36 for indicating the blood flow measurement. The device, states the Examiner, further includes a PCO2 sensor (citing col. 5, line 55 for support). Further, the Examiner states that it is his position that there would also be an indicator for indicate the PCO2 measurement, given that the reference provides an indicator for all other measured values and that he takes official notice that it is well know to display measurement values in medical devices, to inform the user of the patient's condition and, therefore, the degree of systemic perfusion could then be deduced from the indicator.

Applicants disagree and traverse the rejection. Rosenberg et al. disclose that fluid flow detectors are useful for microvascular monitoring, i.e. for monitoring minute variations in the blood flow through skin or other tissue. Detection of minute variations in blood flow at the

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capillary level is useful in the diagnosis of tissue viability, such as burns, tissue trauma, ischemia, and the like and central and peripheral circulation disorders. Col. 1, lines 6-16. The device also may further include a PCO<sub>2</sub> sensor. "In addition, the microvascular monitor head could include means for collecting other data commonly included in such heads, such as . . . partial pressure of carbon dioxide (PCO<sub>2</sub>)." Col. 5, line 55. However, contrary to the Examiner's assertion, Rosenberg et al. do not disclose what that PCO<sub>2</sub> data may be used for. In fact, *no where* in his specification does Rosenberg et al. disclose that his detector device may be used to detect the degree of *systemic* perfusion or *systemic* perfusion failure in a patient. Rather, Rosenberg et al. disclose "An object of the present invention is to provide a detector for detecting fluid flow through an object, where detector is particularly useful for *microvascular* monitoring, i.e. for monitoring minute variations in the blood flow through skin or other tissue . . ." Col. 1, lines 7-11 By monitoring minute variations in the blood flow, Rosenberg et al. is able to determine localized activity such as tissue trauma and ischemia and circulation disorders. Rosenberg et al. do not disclose that the microvascular monitor is capable of detecting the degree of systemic perfusion. In order to anticipate, a reference must disclose each and every limitation of the claimed invention. Rosenberg et al. does not.

Applicants have amended to claim 1 to recite that the blood flow sensor means and the PCO<sub>2</sub> means, when positioned adjacent a mucosal surface, indicates a measured blood flow and a measured PCO<sub>2</sub>, and that "a measured blood flow in the adjacent tissue that is substantially lower than a normal blood flow and a PCO<sub>2</sub> measurement that is substantially higher than a normal PCO<sub>2</sub> measurement is indicative of the degree of systemic perfusion of the patient." Rosenberg et al. do not disclose, teach or suggest that "a measured blood flow in the adjacent tissue that is substantially lower than a normal blood flow and a PCO<sub>2</sub> measurement that is substantially higher than a normal PCO<sub>2</sub> measurement is indicative of the degree of systemic perfusion of the patient." It is believed that with the amendment to claim 1 it is allowable over the art of record. Similar amendments have been made to claims 33 and 38 and it is believed that these claims also distinguish over Rosenberg et al. With regard to dependent claims 2-29 and 34-35, because the independent claim from which they depend patentably distinguishes over the art of record, so too do the dependent claims. Reconsideration is respectfully requested.

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**4. Rejection under 35 U.S.C. §103(a)**

The Examiner rejected claim 30 under 35 U.S.C. §103(a) as being unpatentable over Rosenberg et al. in view of Riccitelli et al. The Examiner states that Riccitelli et al. further teach that it is known to monitor pH and PCO<sub>2</sub> in the same intravascular measuring device and as such it would have been obvious to modify Rosenberg et al. to include a pH sensor. Applicants believe they patentably distinguish over the primary reference, and thus neither Rosenberg et al. alone or in combination with Riccitelli et al. teach or suggest "wherein a measured blood flow in the adjacent tissue that is substantially lower than a normal blood flow and a PCO<sub>2</sub> measurement that is substantially higher than a normal PCO<sub>2</sub> measurement is indicative of the degree of systemic perfusion of the patient."

The Examiner further rejected claims 31 and 32 under 35 U.S.C. §103(a) as being unpatentable over Rosenberg et al. in view of Boggett. The Examiner states that Boggett et al. further teaches that in a microvascular monitoring device like that of Rosenberg, it is known to monitor the rate of change of blood flow and as such, it would have been obvious to modify Rosenberg to include a rate of change of flow determining device. Applicants believe they patentably distinguish over the primary reference, and thus neither Rosenberg et al. alone or in combination with Boggett et al. teach or suggest "wherein a measured blood flow in the adjacent tissue that is substantially lower than a normal blood flow and a PCO<sub>2</sub> measurement that is substantially higher than a normal PCO<sub>2</sub> measurement is indicative of the degree of systemic perfusion of the patient."

The Examiner also rejected claims 33-37 as being unpatentable over Millar stating that Millar shows a device including a blood flow sensor and a sensor holder that is capable of holding the device in place. With regard to claim 37, the Examiner states that Millar teaches a device with a flow sensor and a pH sensor. Applicants traverse the rejection. Millar does not teach or suggest that "a measured blood flow in the adjacent tissue that is substantially lower than a normal blood flow and a PCO<sub>2</sub> measurement that is substantially higher than a normal PCO<sub>2</sub> measurement is indicative of the degree of systemic perfusion of the patient" as now recited by claim 37.

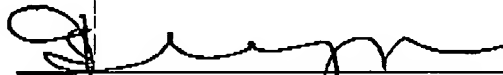
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All rejections and objections being addressed, it is believed that the claims are now in condition for allowance. Reconsideration and allowance are respectfully requested. If the Examiner believes that a teleconference would be of value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below. Applicants' response is being filed within the three-month statutory deadline of February 17, 2006 and it is believed that no additional fees are required. If for some reason it is determined that additional fees are required, the Commissioner is hereby authorized to charge any fees or overpayment to Deposit Account No. 50-1901 (Docket 11242-320).

2/17/06

Respectfully submitted,



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